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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,471	05/22/98	MURPHY	P 5371.31.US02

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EXAMINER	
ZITOMER, S	
ART UNIT	**PAPER NUMBER**
1655	3

DATE MAILED: 09/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/084,471	MURPHY et al.
Examiner	**Group Art Unit**
Stephanie Zitomer	1655

☒ Responsive to communication(s) filed on *May 22, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *ONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

RESTRICTION & NOTICE TO COMPLY

Disposition of Claims

☒ Claim(s) *1-60* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-60* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to comply/Sequence listing error report

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

RESTRICTION AND ELECTION OF SPECIES

Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 22, 24, 26, 28, 30, 38 and 52-54, drawn to DNA, classified in class 536, subclass 23.1;

II. Claims 17-21, 23, 25, 27, 29, 31, 55, 56, 58 and 59, drawn to protein, classified in class 530, subclass 350;

III. Claims 32-37 and 39, drawn to a DNA detection method, classified in class 435, subclass 6;

IV. Claim 40, drawn to a microchip oligonucleotide array, classified in class 536, subclass 24.3;

V. Claims 41-46, drawn to gene therapy method, classified in class 514, subclass 44;

VI. Claims 47-51, drawn to a method of treating with a tumor growth inhibitor, classified in class 514?, subclass unclassifiable;

VII. Claims 57 and 60, drawn to a diagnostic reagent, classified in class 536, subclass 24.3 or class 530, subclass 350. This group requires an election of species: see below.

2. Inventions I, II, VII and III, V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the DNA can be used in other processes such as propagation and protein production via cloning and in immunoassays or methods for producing antibodies.

3. Inventions IV and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MEP. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the

subcombination as claimed because array can be made with other oligonucleotides or antibodies. The subcombination has separate utility such as probes in solution hybridization assays.

.4. Inventions I, II, IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the different inventions are different nucleic acid and protein products having different functions, *viz.*, the nucleic acid of Inventions I, IV and VII functions as a coding sequence and as a hybridization probe or primer; the protein of Inventions II and VII differs in chemical structure from the nucleic acid and functions differently as an enzyme or immunogen or antibody.

5. Inventions III, V and VI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the method of Invention I operates by nucleic acid amplification and has the effect of detecting a nucleotide sequence whereas the method of Invention V operates by administering gene therapy to a patient and the Invention VI method operates by administering a tumor growth inhibitor to a patient, the latter two methods having the potential effect of shrinking the tumor.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for any one Invention group is not required for any other Invention group , restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(l).

Election

10. Claims 57 and 60 are generic to a plurality of disclosed patentably distinct species comprising DNA ((a) and (c)), a nucleic acid fragment ((b) and (c)) and protein ((d)-(e)). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Invention VII will be combined with another Invention according to applicant's elected species. **The nonelected species must be deleted from claim 57.**

NOTICE TO COMPLY WITH SEQUENCE LISTING REQUIREMENTS

11. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CAR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CAR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CAR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CAR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period.

Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Contact information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephanie W. Zitomer, Ph.D.
August 31, 1999

STEPHANIE W. ZITOMER
PRIMARY EXAMINER